DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 23, 2015

Vertera, Incorporated
Mr. Stephen Laffoon
Director of Engineering
311 Ferst Drive NW, Suite L1328
Atlanta, Georgia 30332

Re: K143685
Trade/Device Name: Hedgehog Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: September 21, 2015
Received: September 21, 2015

Dear Mr. Laffoon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K143685

Device Name: Hedgehog Cervical Interbody Fusion Device

Indications for Use:

The Hedgehog Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the interior graft window. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date Submitted: September 21, 2015

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(e).

A. Submitter:
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B. Company Contact:
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C. Device Information:
Trade Name(s): *Hedgehog* Cervical Interbody Fusion Device

Common Name(s): Cervical Interbody Fusion Device

D. Classification Name: Intervertebral Body Fusion Device, 888.3080

E. Product Code: ODP, Intervertebral Body Fusion Device, Cervical

F. Predicate Device(s): Spinal Elements, *Crystal*®, K133218

G. Physical Description:
The proposed *Hedgehog* Cervical Interbody Fusion Device is a sterile, single use implant grade polyetheretherketone (PEEK) device, available in varied footprints and heights, designed for supplemental stabilization of the cervical spinal column in anterior cervical discectomy and fusion (ACDF) procedures.

The *Hedgehog* Cervical device is comprised of a single, continuous piece of PEEK Scoria™ formed into the final product shape. The Vertera device remains solid with a surface porous layer on the top surface of the implant body. This porous surface is derived directly from the implant body and is not a sintered or otherwise additive coating. In addition to PEEK, the cage assembly will have two marker bands, made from Tantalum, to enable visibility under x-ray.

H. Indications for Use:
The *Hedgehog* Cervical Interbody Fusion Device is indicated for use as an intervertebral body fusion device in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) at one level of the

cervical spine with accompanying radicular symptoms. Implants are used to facilitate fusion in the cervical spine (C3-C7) and are placed via an anterior approach using autogenous bone as graft material for the interior graft window. The device is intended to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

I. Comparison of Technological Characteristics:

The *Hedgehog* Cervical Interbody Fusion Device is substantially equivalent in function and intended use to the following predicate device:

Spinal Elements, *Crystal*® K133218

All devices are comprised of implant grade PEEK and utilize tantalum markers. All devices have the same indications for use.

J. Non-Clinical Testing

In addition, functional performance testing has been conducted per applicable standards as recommended in the guidance document. These are (ASTM) F2077-11, *Test Methods for Intervertebral Body Fusion Devices* in static and dynamic compression and torsion, (ASTM) F2267-04, *Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression*, (ASTM) F1877-05, *Standard Practice for Characterization of Particles,* and Expulsion Testing. Non-clinical testing has demonstrated substantially equivalent performance to predicate devices.

K. Conclusion

Analysis of the results supports the conclusion that the proposed device is substantially equivalent to the predicate devices.